REMARKS

This Response Under 37 CFR §1.115 is respectfully submitted in response to the Office Action rendered March 28, 2006. This Response is timely in view of the concurrently filed Petition for Extension of Time. Claims 15-22 are pending and Claims 1-14, 17 and 23-29 are canceled.

The Office Action of March 28, 2006 again rejected Claim 22 under 35 U.S.C. §102(a) as being as anticipated by Kelly et al. (WO 99/36050) ("Kelly"). Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

The Office Action indicates that Kelly et al. teach "that the ratio of organic solvent...in water may be as low as 0.1%" in the extraction process set forth therein [Office Action, p. 3]. The PTO argues that such a low ratio of ethanol would be unlikely to denature proteins therein. Notwithstanding the discussion set forth in the Office Action, applicants respectfully submit that Kelly et al. does not disclose a "non-denatured" whole soy product as alleged in the Office Action. Applicants respectfully point out that the isoflavone products of Kelly et al. would not contain the STI activity of the non-denatured soy extracts of applicants' invention. As set forth in the accompanying Declaration of Miri Seiberg respectfully submitted herewith, alcohol is known to be a denaturant for soy proteins. The accompanying reference, Bau, H.M. and Alais, C., "Denaturation and enzymatic proteolysis *in vitro* of protein fractions from soybean flour", Ann. Nutr. Alim.: 1975, **29**, 351-370, sets forth (see translation at page 4):

> Denaturation by means of ethyl alcohol was carried out by stirring 1 g of the protein fraction with 10 mL of a 0 to 100 percent solution of alcohol; after a 24 hour period of contact, the ethanol was evaporated and the residue was dried by means of lyophilization.

Thus, it was well-known that ethyl alcohol was an agent that would denature the protein fraction of soy prior to applicants' invention.

Applicants respectfully submit that the soy extract set forth in Kelly is **not** non-denatured and the recitation of a "non-denatured" soy product is not inherent in Kelly as

the Office Actions asserts. Applicants therefore respectfully request reconsideration of the foregoing rejection.

The Office Action of March 28, 2006 again rejected Claims 15-21 as being unpatentable over Tokuyama (JP 5-320061), in view of Mizue (JP 62-36304). The Office argues that "the Tokuyama reference teaches the same extraction method as disclosed in the instant application. See Examples 2 and 3. Therefore, the soy product of Tokuyama is non-denatured because it is produced by the same method as disclosed herein." [Office Action, p. 4]

Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

Applicant respectfully submits that the products set forth in Tokuyama are different from those claimed in instant application. Tokuyama did not recognize the importance of maintaining the STI activity and is not concerned that the extract retains serine protease inhibitory activity. Tokuyama describes the extracted activity as "unknown component [which] is stable in the presence of heat" (p.3), whereas STI, which provides activity in the claimed invention, is known to be heat labile. (Declaration of Miri Seiberg, ¶5)

Moreover, Tokuyama uses high temperatures "in extraction by boiling..." (Tokuyama, p.3) and other extraction procedures such as extreme pH or organic solvents (..."pretreatment with an acid or alkali"... (p.4), ..."processed in organic solvent extraction"), all of which processes are known to denature proteins, thereby eliminating STI's protease inhibitory activity.

Nor does Mizue compensate for the inadequacies of Tokuyama in directing those of ordinary skill in the art toward applicants' claimed invention. The Office Action relied on Mizue to teach stabilizing soy extracts in cosmetic compositions with preservatives such as parabens and chelating agents such as disodium EDTA. [Office Action, p. 5] The Office Action than concluded that it would have been obvious to one having ordinary skill in the art at the time of the invention was made to modify the cosmetic or dermatological soy extract-containing compositions of Tokuyama to add chemical agents such as preservatives.

Applicants respectfully submit that Mizue, taken together with Tokuyama or separately, would not render the compositions and methods of applicants' invention obvious. Although Mizue discusses means for preserving soy extracts present in a composition, it does not provide means for obtaining the non-denatured, active STI-containing extracts of the compositions of applicants' invention. Rather, Mizue teaches stabilization in terms of *prevention* of degradation or decomposition. Mitzue does not teach stabilization of *proteins*, which could be intact but inactive upon denaturation.

Mizue does not recognize providing non-denatured soy extracts at the beginning of the preservation process, nor does it describe or suggest any protein-containing compositions, which have the unique properties of conformation-dependent activity. Although Mizue does set forth means for ensuring that the soy extracts therein do not decompose, there is no suggestion or disclosure that the STI-type proteins are present in Mizue's soy extracts to begin with. Processing the non-denatured soy extracts of applicants' invention ensures that the appropriate proteins are present in the extract, no matter how they are preserved. Those who follow Mizue's suggestion of adding chelating agents or parabens in order to preserve soy extracts can only preserve what is already present in the extract. This is similar to the difference between freezing a piece of raw meat and freezing a beef stew: both processes preserve the meat, but *all* the original components of raw meat are present in the raw meat, while the beef stew has been cooked and therefore is missing some components and is different. In the case of Tokuyama, the extract therein is not a non-denatured extract. To combine Tokuyama with Mizue would not have lead to a topical, skin care composition comprising a soy product in which the soy product was a non-denatured soy product. Neither Tokuyama nor Mizue describes or suggests compositions containing *active proteins.*

In view of the foregoing discussion, applicants respectfully request reconsideration of the rejections set forth in the Office Action of March 28, 2006. An early allowance is earnestly solicited. Kindly direct any questions or contacts to the undersigned.

Respectfully submitted,

/Andrea L. Colby/

By:_____

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DATE: August 21, 2006

L3: Entry 48 of 69 File: DWPI Feb 16, 1994

DERWENT-ACC-NO: 1995-162353
DERWENT-WEEK: 199522

TITLE: Broad-spectrum ointment

INVENTOR: CUI, S; WANG, L

PATENT-ASSIGNEE:

ASSIGNEE	CODE
WANG L	WANGI

PRIORITY-DATA: 1993CN-0104974 (April 24, 1993)

PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
CN 1081899 A	February 16, 1994		001	A61K035/78

APPLICATION-DATA:

PUB-NO	APPL-DATE	APPL-NO	DESCRIPTOR
CN 1081899A	April 24, 1993	1993CN-0104974	

INT-CL (IPC): A61K 9/06; A61K 35/78

ABSTRACTED-PUB-NO: CN 1081899A
BASIC-ABSTRACT:

A Chinese ointment 'Guanglinggao' for curing sores, psoriasis, dermatosis, skin cancer, piles, rectal cancer, uterine cancer, metritism, tympanitis is prepd. with 8 raw materials including sea-ear shell, wild chrysanthemum flower, wild gastrodia tuber, pure grain wine, pure soybean oil, etc. It features high curative effect, no surgery, no hospitalisation, safe in administration and low cost.

CHOSEN-DRAWING: Dwg.0/0

TITLE- TERMS: BROAD SPECTRUM OINTMENT

DERWENT-CLASS: B04

CPI-CODES: B04-A08C2; B04-A10C; B04-B01C1; B04-B04M; B14-H01; B14-N17;

SECONDARY-ACC-NO:
CPI Secondary Accession Numbers: C1995-075241

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L3: Entry 46 of 69 File: DWPI Apr 9, 1997

DERWENT-ACC-NO: 2001-103707
DERWENT-WEEK: 200241

TITLE: Beauty bean milk

INVENTOR: LI, Z

PATENT-ASSIGNEE:

ASSIGNEE	CODE
LI Z	LIZZI

PRIORITY-DATA: 1995CN-0111825 (June 28, 1995)

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PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
CN 1146876 A	April 9, 1997		000	A23L002/38

APPLICATION-DATA:

PUB-NO	APPL-DATE	APPL-NO	DESCRIPTOR
CN 1146876A	June 28, 1995	1995CN-0111825	

INT-CL (IPC): A23 L 2/38

ABSTRACTED-PUB-NO: CN 1146876A
BASIC-ABSTRACT:

NOVELTY - A beautifying beverage is prepared from almond, coix seed, black sesame, raisin, jujube, haw, wolfberry fruit, small red bean, honey, carrot, tea, soybean and water, and contains protein, amino acids, niacin, VA, VB, VC, VD, VE, Fe, P, Ge and Ca. Its medical functions include preventing and treating acne and ephelis, blackening and protecting hair, reducing blood fat and cholesterol, and promoting blood circulation.

CHOSEN-DRAWING: Dwg.0/0

TITLE-TERMS: BEAUTY BEAN MILK

DERWENT-CLASS: D13 D21

CPI-CODES: D03-B; D08-B09A;

UNLINKED-DERWENT-REGISTRY-NUMBERS: 0035U; 0179U ; 0190U ; 0282U

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L3: Entry 45 of 69 File: DWPI Dec 10, 1997

DERWENT-ACC-NO: 2001-583056
DERWENT-WEEK: 200166

TITLE: Composite beauty masque powder containing spirulina

INVENTOR: JIN, J

PATENT-ASSIGNEE:

ASSIGNEE	CODE
JIN J	JINJI

PRIORITY-DATA: 1996CN-0107835 (June 4, 1996)

PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
CN 1166960 A	December 10, 1997		000	A61K007/48

APPLICATION-DATA:

PUB-NO	APPL-DATE	APPL-NO	DESCRIPTOR
CN 1166960A	June 4, 1996	1996CN-0107835	

INT-CL (IPC): A61 K 7/48

ABSTRACTED-PUB-NO: CN 1166960A
BASIC-ABSTRACT:

NOVELTY - The invented powder consists of spirulina, pearl powder, pure pollen, mung bean flour, separated protein powder of soybean, white stiff silkworm powder and talcum powder and is made up through the process of crushing, mixing and bactericidal treatment. The advantages is that when said beauty masque powder is applied on face, the masque is formed after several minutes, once every day and each nursing time is only about 0.5 hour, after one-two times of nursing, the smooth, fine, white, tender complexion begins to appear, after applying 3-7 times, the acne or chloasma can be obviously decreased,there is no side effect.

CHOSEN-DRAWING: Dwg.0/0

TITLE-TERMS: COMPOSITE BEAUTY POWDER CONTAIN SPIRULINA

DERWENT-CLASS: D21

CPI-CODES: D08-B;

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L3: Entry 37 of 69 File: JPAB Aug 25, 1998

PUB-NO: JP410226642A
DOCUMENT-IDENTIFIER: JP 10226642 A
TITLE: THERAPEUTIC AGENT FOR SKIN MULTIPLICATION DISEASE

PUBN-DATE: August 25, 1998

INVENTOR-INFORMATION:
NAME COUNTRY
KATAOKA, SHIGEHIRO
MANAKA, TATSUO
SOMEYA, TAKAO
OBATA, AKIO

ASSIGNEE-INFORMATION:
NAME COUNTRY
KIKKOMAN CORP

APPL-NO: JP09048552
APPL-DATE: February 18, 1997

INT-CL (IPC): A61 K 31/35; A61 K 7/00; A61 K 7/06; A61 K 7/48; C07 D 311/36

ABSTRACT:

PROBLEM TO BE SOLVED: To obtain a secure excellent agent for preventing and treating skin mutiplication disease and a cosmetic material by formulating a genistein active ingredient with a therapeutic agent for skin disease and a cosmetic material.

SOLUTION: Genistein used is obtainable by synthesis, extraction from soy lees and soy oil, fermentation using microorganisms and also extraction from beans such as soybean and the like. As therapeutic agents for psoriasis, ichthyosis, keratosis and dandruff disease caused by excess multiplication of skin, 0.01-5 w/w% may be applied when administrated to a lesion part as an ointment, and about 20-1000mg may be at once administrated several times a day for adult when used as a peroral drug. When used as a cosmetic material, if there is no obstacle in use, even the low concentration product extracted from soybeans and soy lees in place of pure genistein is usable.

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L6: Entry 34 of 37 File: DWPI Oct 8, 1992

DERWENT-ACC-NO: 1992-385398
DERWENT-WEEK: 199247

TITLE: Anti-periodontal disease agents inhibiting proliferation of Bacteroides gingivitis - obtd. by soaking soybean(s) in water to extract iso:flavone glycoside (s) including genistein glycoside

PATENT-ASSIGNEE:

ASSIGNEE	CODE
KIKKOMAN CORP	KIKK

PRIORITY-DATA: 1991JP-0070389 (March 12, 1991)

PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
JP 04283518 A	October 8, 1992		003	A61K038/78

APPLICATION-DATA:

PUB-NO	APPL-DATE	APPL-NO	DESCRIPTOR
JP 04283518A	March 12, 1991	1991JP-0070389	

INT-CL (IPC): A61K 38/78

ABSTRACTED-PUB-NO: JP 04283518A
BASIC-ABSTRACT:

Anti-periodontal disease agents contain genistein.

Genistein is prepd. by soaking peeled soybeans in water of pH 8-11 at 50-60 deg.C to extract isoflavon glycosides including genistein glucoside. This extract is hydrolysed with enzyme or acid and the hydrolysate is filtered through ultrafiltration membrane to give a fraction contg. isoflavones. Crude genistein may be purified by adsorption-elution process by use of proper resins or by extn. with ether. Genistein obtained can be mixed in tooth paste, gargle, chewing gum, or troche.

USE/ADVANTAGE - The agents inhibit the proliferation of B. gingivalis which is adherent bacteria in the bronchial and intestinal tracts and causes varied periodontal disorders including periodontosis. Genistein is the aglucon of genistein and other isoflavon glucosides which can be easily obtd. and is of low toxicity. The glucosides are readily gained from plants such as soybeans, e.g. by means of extn..

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